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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,197	02/01/2002	Lan Bo Chen	00530-097001/ 731.02	9895
26161	7590	07/26/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			MAHATAN, CHANNING	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/062,197

Applicant(s)

CHEN ET AL.

Examiner

Channing S Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 8-16 and 20-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 17-19 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/30/03 & 9/30/02</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

APPLICANTS' ELECTION

Applicant's election with traverse of Group I (claims 1-7; drawn to a method of detecting the presence or absence of a target body in a specimen) in the reply filed on 28 May 2002 is acknowledged. Further, it is acknowledged the Examiner agreed to consider claims 17-19 (Groups VI and VII) together with claims 1-7; if said claims are amended to reflect proper dependency. Applicants have adequately amended claims 17-19, and thus said claims are herein grouped with claims 1-7. No other arguments for the 'election with traverse' are presented with regard to the inventions of Groups I-V and VIII. Therefore, with respect to Groups I-V and VIII the requirement is still deemed proper and is therefore made FINAL.

Claims 8-16 and 20-28 are withdrawn from further consideration pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-7 and 17-19.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 17-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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VAGUE AND INDEFINITE

Claims 1 and all claims dependent therefrom are indefinite due to the lack of clarity of the claim language failing to recite a final process step, which agrees back with the preamble. The preamble states that it is “A method of detecting the presence or absence of a target body in a specimen”, however the claim recites a final step of “inspecting a first image and second image at a single location within the specimen field, wherein the presence of a candidate body in the first and second images at the single location indicates the presence of a target body in the specimen. There is no indication that the absence of a target body is to be detected as recited in the preamble. While minor details are not required in method/process claims, at least the basic step must be recited in a positive, active fashion. The claim does not set forth the conditions/state when the absence of a target body is detected. Clarification of the metes and bounds of the claim is requested via clearer claim wording.

Claim 1 and all claims dependent therefrom recite the limitations “low magnification” and “high magnification” which are vague and indefinite. The terms “low” and “high” imply ranges or values of magnification that is consider to be of “low” and “high” magnification. For example, one may consider “low” magnification to be of the range 1X to 100X whereas someone else may consider “low” magnification to be only 1X. Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 1 and all claims dependent therefrom recite the limitation “an optical or electronic filter substantially blocks photons” which is vague and indefinite. It is unclear the degree(s)/parameter(s) that Applicants’ deem “substantially” to encompass. For instance, “substantially blocks photons” may be considered to embrace completely blocking photons or

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blocking only one photon. Applicants can resolve this issue by particularly pointing out what “substantially” is intended to encompass. Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 3 and all claims dependent therefrom recite the limitation “a dye sensitive for dead cells” which is vague and indefinite. It is unclear the criteria by which Applicants’ regard a dye to be “sensitive” for dead cells. Applicants’ can resolve this issue by particularly pointing out the criteria(s) that establishes such sensitivity. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 17-19 are rejected under 35 U.S.C. § 102(a) as being anticipated by

Kraeft et al. (Detection and Analysis of Cancer Cells in Blood and Bone Marrow Using a Rare Event Imaging System. Clinical Cancer Research. February 2000, Volume 6, pages 434-442.

Kraeft et al. describe an automated rare event detection system (Rare Event Imaging System) for the recognition of cancer cells that appear at low frequencies (1 in 1 million) in peripheral blood (PB) or bone marrow (BM) (claims 4 and 17-19; Abstract). Slides are scanned at low magnification for the detection of tumor cells based cytokeratin/rhodamine labeling and total cell count (claim 1; page 435, left column, lines 40-59; and page 436, left column, lines 28-

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45). The authors describe the procedures for the preparation of the specimen: 1) lysis of blood or bone marrow samples; 2) centrifugation of said lysis sample; 3) obtainment of cell pellet (separation from supernatant); 4) resuspension of the cell pellet in buffer (PBS); 4) counting total number of living cells using trypan blue dye exclusion; 5) attachment of cells to adhesive slides; and 6) blocking of cell with cell culture medium (claims 2 and 3; page 435, right column, lines 20-29; and page 438, right column, lines 3-20). The total number of cells applied per slide was 1.5×10^6 (claim 5; page 436, right column, lines 29-30). Further, sensitivity regarding tumor cell detection was determined by serial dilutions prior to attachment to adhesive slides and processing (claim 3; page 436, left column, lines 7-16). Images were obtained utilizing an automated fluorescence microscope (Nikon Microphot-FXA) with a cool charge coupled device camera and a 60-MHz Pentium personal computer (claim 6, i.e. 1024 x 1024 image; Abstract; and page 436, lines 18-26). The authors indicate stained cells could easily be distinguished from the background of white blood cells (WBCs), wherein said WBCs represent the majority of cell types (i.e. 26 labeled cells/ 10^6 WBCs) (claim 7; Figure 1A; and page 437, right column, lines 17-20). Thus, Kraeft et al. anticipate the instantly claimed invention.

OBJECTION TO CLAIM

Claim 6 is objected to because of a spelling error, wherein “recoding” should be replaced with “recording”. Appropriate correction is requested.

OBJECTION TO DISCLOSURE

The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains embedded hyperlinks and/or other form of browser-executable code; for example, page 17, lines 24; page 23, lines 30; page 24, lines 12,

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15, and 16). Applicants are required to delete the embedded hyperlinks and/or other form of browser-executable code. Applicants are requested to review the application for embedded hyperlinks and/or other forms of browser-executable code and delete them. Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference. See M.P.E.P. § 608.01 and 608.01(p). Applicants are to note a “www” format will yield an executable hyperlink, thus, a suggested format is “World Wide Web”.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify Applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables Applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Date: July 21, 2004
Examiner Initials: CSM

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
7/20/04
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